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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,911	09/18/2001	Arun B. Kulkarni	J&J-2049	8616

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EXAMINER

LAMM, MARINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/954,911	Applicant(s) KULKARNI ET AL.	
	Examiner Marina Lamm	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 6, 8, 9 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 8, 9 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the amendment filed 9/30/05. Claims pending are 1, 4, 6, 8, 9 and 13-17. Claims 1, 4, 6 and 8 have been amended. Claims 2, 3, 5, 7 and 10-12 have been cancelled.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 4, 6, 8, 9, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Picken, Jr. et al. (US 6,194,372), of record.

Picken, Jr. et al. teach sprayable gel compositions capable of liquefying upon shearing, said compositions containing 1-4% of a clay thickener, 5-26% of a solvent including glycols such as propylene glycol, dibasic esters and alcohols such as ethanol, and the like, builders (viscosity stabilizers) such as EDTA, citrus water distillate, surfactants, coloring agents, terpens and other additives. See Abstract; col. 1, lines 61-65; col. 3-4. With respect to Claims 13, 15 and 16, the reference teaches 0.5-2% of a preservative. The preservatives of Picken, Jr. et al. include chloroxylenol which is a conventional anti-fungal and anti-microbial agent. See col. 4, lines 43-45. The reference does not explicitly teach the claimed concentration of the viscosity stabilizer (builder), such as EDTA. However, the determination of optimal or workable concentration of the viscosity stabilizer (builder) by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have

been motivated to do this to obtain the desired viscosity and/or stability of the gel. Further, the reference teaches from about 5% to about 26% by weight of the polar solvents, but fails to teach the claimed concentration of "from about 30 percent to about 65 percent by weight" (Claim 1) and "from about 35 percent to about 50 percent by weight" (Claim 8). However, the determination of optimal or workable concentration of the polar solvent by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired viscosity of the composition. Further, the recitation "about 5 to about 26%" in the reference allows for concentrations slightly above 26% and the recitation of "about 30%" or "about 35%" in the instant claims allows for concentrations slightly below 30% and 35%, so the ranges overlap. See *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

3. Claims 1, 4, 6, 8, 9, 13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagida et al. (US 5,484,816), of record.

Yanagida et al. teach skin treatment compositions containing active agents such as vitamin A, clays such as hectolite and saponite, glycerol, propylene glycol, ethanol, water and acids and/or salts such as citric acid, ascorbic acid, sodium edetate and sodium isoascorbate. See col. 9, lines 9-47; col. 46, Examples 14-2, 14-8. In particular, Example 14-2 (in Table 14-1) exemplifies a composition comprising water, 10% of glycerol, 5% of ethanol, 0.03% of trisodium edetate, 2% of clay gelling agent (natural montmorillonite) and 0.3% of active agent (vitamin A). Example 14-11 at col. 46

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exemplifies a composition containing 28% of polar solvents such as glycerol, propylene glycol and ethanol, in combination with clay gelling agents, citric acid, skin care actives and water. The Yanagida et al. reference teaches that the amount of clay may be as little as 0.01%, preferably 0.1%, and not exceeding 50% by weight, depending on the desired gelling effect. See col. 9, lines 38-47. While exemplifying compositions containing various concentrations of glycols and/or alcohols, the reference does not explicitly teach the claimed concentration of "from about 30 percent to about 65 percent by weight" (Claim 1) and "from about 35 percent to about 50 percent by weight" (Claim 8). However, the determination of optimal or workable concentration of glycols and/or alcohols by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired moisturizing properties and/or viscosity of the composition. Further, the recitations of "about 30%" or "about 35%" in the instant claims allows for concentrations slightly below 30% and 35% and indicate that the upper and lower limits of the concentration range are not critical to distinction over prior art.

4. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagida et al. (US 5,484,816) in view of Kamishita (US 4,543,251), both of record.

Yanagida et al. applied as above. While teaching antioxidants and other skin care active agents, the reference does not teach menthol or camphor of the instant claims. However, Kamishita teaches using menthol in topical compositions to "impart a cool

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feeling to the skin." See col. 3, lines 40-45. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the topical composition of Yanagida et al. such that to add menthol. One having ordinary skill in the art would have been motivated to do this to obtain formulations that impart a cool feeling to the skin as suggested by Kamishita.

Response to Arguments

5. The rejection of Claims 1, 3, 5, 6, 9, 13, 15 and 16 under 35 U.S.C. 102(b) as being anticipated by Yanagida et al. is withdrawn in view of the amendment to Claim 1.

6. Applicants' arguments filed 9/30/05 with respect to the 103 rejection of the instant claims over Yanagida et al. have been fully considered but they are not persuasive.

The Applicants argue: "...Yanagida does not address a shear thinning, sprayable gel compositions as claimed by Applicants, nor is there any indication in Yanagida that gels disclosed therein are shear thinning or sprayable. Accordingly, Applicants respectfully submit that Yanagida, as a whole, fails to provide any suggestion or teaching to one skilled in the art as to compositions claimed by Applicants." See p. 5 of the reply.

In response, the recitation "shear thinning sprayable" has not been given patentable weight because the recitation occurs in the preamble. It appears, however, that the exemplified beauty gels, lotions and essences of Yanagida et al. would meet such limitation because they contain same ingredients in similar proportions (i.e. clay gelling agent(s), glycols and/or alcohols, viscosity stabilizer(s), etc., that would impart the recited properties of the compositions. Alternatively, the Applicant is invited to

recite what specific ingredients/proportions make their compositions, unlike the compositions of the prior art, "shear thinning" and "sprayable".

Further, the Applicant argues: "Upon a thorough review of Examples 14-1 through 14-11, nowhere is there disclosed or suggested compositions that include clay gelling agents, viscosity stabilizers and water-miscible solvents, each as claimed by Applicants and each in the relative amounts as claimed by Applicants." See pp. 6-7 of the reply.

In response, Yanagida et al. exemplifies the claimed combination of polar solvents such as glycerol, propylene glycol and ethanol, in combination with clay gelling agents, citric acid, skin care actives and water. See Example 14-11 at col. 46. The concentration of the polar solvents in the Example is 28% by weight; the concentration of clay gelling agents is 4% by weight; the concentration of citric acid is 0.03% by weight. Further, reference teaches that the amount of clay may be as little as 0.01%, preferably 0.1%, and not exceeding 50% by weight, depending on the desired gelling effect. See col. 9, lines 38-47. It is the Examiner's opinion that the determination of optimal or workable concentration of polar solvents and clay gelling agents by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired viscosity of the composition as discussed above.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

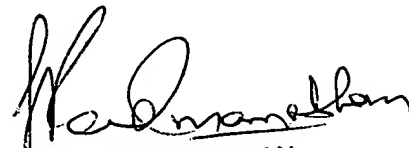
The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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Marina Lamm
12/11/05



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SUPERVISORY PATENT EXAMINER